CERTIFICATE OF USPTO ELECTRONIC FILING SYSTEM SUBMISSION
I hereby certify that this correspondence is being transmitted herewith via the USPTO's Electronic Filing System (EFS-Web) on the date indicated below and is addressed to: MAIL STOP: RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Submission: November 11, 2010

Selena Whitaker Paquiet

Attorney Docket No. 24900.1018
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: **Xin QI and Richard TESTER**

Group Art Unit: 1612

Application No.	:	10/578,551
Filed	:	June 29, 2006
For	:	**COMPOSITIONS AND USES THEREOF**
Examiner	:	Nannette Holloman

DECLARATION OF PROFESSOR RICHARD TESTER

MAIL STOP: RCE
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

The undersigned, Professor Richard Frank Tester, hereby declares:

1. I am Professor of Carbohydrate Chemistry at Glasgow Caledonian University, UK, and Managing Director at Glycologic Limited, the assignee of record of the subject patent application, and an inventor of the subject matter disclosed and claimed in the application. I have a Ph.D. in the field of starch chemistry and am the author of over 70 articles in peer-reviewed journals.

2. I have reviewed the Anderson et al. reference (Starch, vol. 54, 2002, pp. 401-409) in detail. The reference makes several contradictory statements regarding the properties of heat moisture treated (HMT) waxy and non-waxy starches prepared using the specific conditions disclosed in the reference. If however, one accepts the statement made by Anderson et al. with respect to the data provided in Fig. 6 that heat moisture treatment causes a very small decrease in the digestibility of waxy and non-waxy corn starch by alpha-amylase and assumes that this would

also be in the case *in vivo*, this would have a detrimental effect on patients suffering from, or susceptible to, hypoglycemia as the amount of starch digested, and therefore the amount of glucose produced, would be reduced. This would in fact result in the patient becoming more hypoglycemic.

In addition, since Anderson et al. gelatinize the starch before use (see section 2.4), their *in vitro* testing is not based on intact starch granules (such as ours) but dispersed starch molecules. The body would in fact digest available amorphous gelatinized starch within about 150 minutes and this could not be used to control hypoglycaemia.

3. As described in Example 6 of the subject application, and supported by the disclosure of Bhattacharya et al. (J. Inherit. Metab. Dis, 30:350-357, 2007) previously provided to the Examiner, and Correia et al (Am. J. Clin Nutr., 88:1272-1276, 2008; copy submitted herewith as Exhibit A) we have demonstrated that the *in vivo* digestive profile of HMT waxy maize starch prepared according to the protocol described in the subject application is quite different and unexpected. This has been further supported within sports nutrition by Roberts et al. (Nutrition, in press, 2010; copy submitted herewith as Exhibit B). Specifically, the initial spike in glucose production upon administration of the starch is reduced and the duration of glucose release is extended. These results could not have been predicted from *in vitro* studies, such as those described by Anderson et al.

4. The attached figure (Exhibit C) shows the variation in blood glucose levels observed over time in a subject following administration of native waxy maize starch and HMT waxy maize starch (at a dosage of 50 or 60g) prepared as described in the subject application, compared to the results that one would expect to obtain if digestibility of HMT starch were reduced as proposed by Anderson et al.

For the study using native waxy maize starch, the resting blood glucose level was around 5 mmol/L. As shown in the figure by the dotted blue line, digestion was complete by 120 minutes. For the study using the inventive HMT waxy maize starch, the resting blood glucose was around 4.2 mmol/L. In this case, as shown by the red dotted line, the digestion time was increased to 420 minutes. In addition, the initial glucose peak was flattened.

If one assumes, as proposed by Anderson et al. for rice starches, that heat moisture treatment reduces digestibility by 25% compared to native starch, one would obtain the profile shown in the attached figure, where blood glucose is decreased by 25% based on the native waxy maize starch. As can be seen in the figure, digestion would be complete by 60 minutes compared to the control and entry into hypoglycemia would be faster than for the native starch.

5. One of skill in the art could not have predicted the *in vivo* digestive profile that is obtained using the inventive HMT waxy maize starch. While not wishing to be held to theory, it appears that the differences in blood glucose control by the inventive HMT waxy maize starch and by native waxy starch are not due to the differences in the rate of amylase hydrolysis but may be due to differences in the rate of transit of the starch through the small intestine and/or differences in the way amylase attaches to the starch, each of which may lengthen the duration of digestion.

6. I thus believe that the teachings of Anderson et al., either by themselves or in combination with the disclosures of US Patent 5,605,893 to Kaufman and/or PCT publication no. WO 02/34271, would not have rendered the presently claimed methods and compositions obvious to one of skill in the art at the time the present invention was made.

4. The undersigned further declares that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements, and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 35 of the United States Code.

R. Tester

Richard Tester

28/10/10

Date